K050813

MAY - 4 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
in Accordance with SMDA of 1990

2ND GENERATION SCREW, ABC CERVICAL PLATING SYSTEM (ABC 2 SCREW)

March 29, 2005

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Kathy A. Racosky, Regulatory Affairs Associate
800-258-1946 (phone)
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TRADE NAME: ABC Cervical Plating System (ABC 2 Screw)

COMMON NAME: Anterior Cervical Screw Spinal Fixation System

DEVICE CLASS: Class II

PRODUCT CODE: KWQ

CLASSIFICATION: 888.3060 - Appliance, Fixation, Spinal Intervertebral Body

REVIEW PANEL: Orthopedics

INTENDED USE

The ABC Cervical Plating System is intended for the treatment of cervical spine instability resulting from degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), post-traumatic kyphosis or lordosis, tumors, and re-operation for failed previous fusions. Levels of anterior cervical intervertebral body screw fixation for this indication are from C2-T1.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

DEVICE DESCRIPTION

The ABC Cervical Plating System consists of two spinal implant components: bone plates and bone screws. Both implants are manufactured from titanium alloy, Ti6Al4V according to ISO 5832/3 and are provided non-sterile. The 2nd generation screw will be self-locking with an internal locking pin and spring.

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The outer body of the 2nd generation screw is still manufactured from Ti6Al4V while the internal locking mechanism is made from Phynox (cobalt alloy) per ISO 5832/7. The specialized ABC instruments are made primarily of surgical grade stainless steel according to ISO 7153/1 and are hand-held, re-usable devices.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The ABC system was tested according to ASTM F2193-02 and the results demonstrated substantial equivalence to the predicate device.

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the 2nd Generation Screw for the ABC Cervical Plating System (ABC 2 Screw) is substantially equivalent to screws cleared for our current Anterior Cervical Screw Spinal Fixation System (K000486). Plates and Screws for the ABC System were originally cleared in K974706.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

Ms. Kathy A. Racosky
Regulatory Affairs Associate
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K050813
Trade/Device Name: ABC Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 18, 2005
Received: April 19, 2005

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: ABC Cervical Plating System

Indication for Use:

The ABC Cervical Plating System is intended for the treatment of cervical spine instability resulting from degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), post-traumatic kyphosis or lordosis, tumors, and re-operation for failed previous fusions. Levels of anterior cervical intervertebral body screw fixation for this indication are from C2-T1.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050813